Notice of Allowability	Application No.	Applicant(s)	
	09/824,053	STOUGAARD ET AL.	
	Examiner	Art Unit	
	William W. Moore	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 9 February, and the interview conducted 5 May 2004*.

2. ☒ The allowed claim(s) is/are *9-13,18,22,25,32-34,45,50-53,58,65-68 and 84*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☒ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☒ Certified copies of the priority documents have been received in Application No. *08/476,910* .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 03/03/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20040505* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Cancel claims 1-8, 22, 26-31, 35-44, 46, 54, 62, and 69-83.

Rewrite claims 9-13, 18, 22, 25, 32, 34, 45, 50-53, 58, 65, 66, 68, and 84:

9. (Currently amended) An isolated DNA fragment comprising a DNA sequence encoding a *Chondrus crispus* ~~polypeptide having~~ hexose oxidase ~~activity, said *Chondrus crispus* polypeptide~~ comprising the internal peptide sequences:

(i) Tyr-Glu-Pro-Tyr-Gly-Gly-Val-Pro (SEQ ID NO:1),

(ii) Ala-Ile-Ile-Asn-Val-Thr-Gly-Leu-Val-Glu-Ser-Gly-Tyr-Asp-~~X-X-X-~~Xaa-Xaa-Xaa-Gly-Tyr-~~X-~~Xaa-Val-Ser-Ser (SEQ ID NO:2),

(iii) Asp-Leu-Pro-Met-Ser-Pro-Arg-Gly-Val-Ile-Ala-Ser-Asn-Leu-~~X-~~Xaa-Phe (SEQ ID NO:3),

(iv) Asp-Ser-Glu-Gly-Asn-Asp-Gly-Glu-Leu-Phe-~~X-~~Xaa-Ala-His-Thr (SEQ ID NO:4),

(v) Tyr-Tyr-Phe-Lys (SEQ ID NO:5),

(vi) Asp-Pro-Gly-Tyr-Ile-Val-Ile-Asp-Val-Asn-Ala-Gly-Thr-~~X-~~Xaa-Asp (SEQ ID NO:6), and

(vii) ~~X-~~Xaa-Ile-Arg-Asp-Phe-Tyr-Glu-Glu-Met (SEQ ID NO :8),

where ~~X~~ Xaa represents an amino acid selected from the group consisting of Ala, Arg, Asp, Cys, Gln, Glu, Gly, His, Ile, Leu, Lys, Met, Phe, Pro, Ser, Thr, Trp, Tyr, and Val.

10. (Currently amended) A ~~An isolated~~ DNA fragment according to claim 9 comprising the hexose oxidase ~~(HOX)~~ coding region set forth in ~~of sequence~~ SEQ ID NO:30.

11. (Currently amended) A microbial host cell transformed with ~~comprising~~ a ~~an isolated~~ DNA fragment according to claim 9 and capable of producing the hexose oxidase encoded by said DNA fragment, wherein the ~~said~~ transformed microbial host cell is ~~being~~ selected from the group consisting of a bacterial cell, a fungal cell and a yeast cell.

12. (Currently amended) A microbial host cell ~~comprising an isolated DNA fragment~~ according to claim 11, wherein the ~~said microbial~~ host cell is ~~being~~ selected from the group consisting of an *E. coli* cell, a *Saccharomyces cerevisiae* cell and a *Pichia pastoris* cell.

13. (Currently amended) An isolated hexose oxidase ~~A polypeptide encoded by an isolated DNA fragment~~ produced according to a method of claim 51 ~~9~~ where the hexose oxidase ~~polypeptide encoded by the isolated DNA fragment~~ is in a substantially non-glycosylated form.

18. (Currently amended) A ~~An isolated~~ DNA fragment according to claim 9 encoding a hexose oxidase which ~~where the polypeptide encoded by the isolated DNA fragment~~ oxidizes at least one sugar selected from the group consisting of D-glucose, D-galactose, maltose, cellobiose, lactose, D-mannose, D-fucose and D-xylose.

22. (Currently amended) An isolated, recombinantly-produced, hexose oxidase encoded by a DNA fragment according to claim 9 wherein the hexose oxidase ~~where the polypeptide encoded by the isolated DNA fragment~~ is in substantially non-glycosylated ~~purified~~ form.

25. (Currently amended) A nucleic acid sequence encoding a fusion polypeptide comprising a hexose oxidase encoded by a DNA fragment according to claim 9 ~~additionally enzymatically active amino acid sequences~~.

32. (Currently amended) A method of manufacturing a food product with a reduced sugar content ~~utilizing a hexose oxidase (HOX) encoded by an isolated DNA fragment~~ comprising,

(i) adding a hexose oxidase according to claim 13 ~~9~~ to the food product prior to, during, or subsequent to a process step, and,

(ii) processing, storing, or packaging the food product comprising the hexose oxidase,

whereby the sugar content of the food product is reduced.

33. (Original) A method according to claim 32 wherein the food product is selected from the group consisting of a dairy product, a starch-containing product and a non-dairy product.

34. (Currently amended) A method ~~according to claim 32 wherein the polypeptide~~ of manufacturing a food product comprising an antioxidant comprising,

(i) adding a hexose oxidase according to claim 13 to the food product prior to, during, or subsequent to a process step, and,

(ii) processing, storing, or packaging the food product comprising the hexose oxidase,

whereby the hexose oxidase acts ~~is acting as an antimicrobial agent or~~ as an antioxidant.

45. (Currently amended) A composition comprising a ~~*Chondrus crispus*~~ hexose oxidase ~~polypeptide encoded by the isolated DNA fragment~~ according to ~~of~~ claim 13 ~~9~~.

50. (Currently amended) A composition comprising a DNA fragment ~~the hexose oxidase (HOX) coding region of sequence (SEQ ID NO:30)~~ according to claim 10.

51. (Currently amended) A method of producing a ~~polypeptide having~~ hexose oxidase ~~activity,~~ comprising isolating or synthesizing a DNA fragment according to claim

9 ~~encoding the polypeptide~~, introducing the DNA fragment into a nucleic acid vector comprising an appropriate ~~expression~~ signal for expression of the encoded hexose oxidase ~~the DNA fragment~~, transforming ~~said DNA fragment into an appropriate~~ a microbial host cell ~~organism~~ with ~~in which~~ the vector comprising the DNA fragment ~~is combined with an appropriate expression signal for the DNA fragment~~, cultivating the transformed microbial host cell ~~organism~~ under conditions leading to expression ~~expressing~~ of the hexose oxidase, ~~active polypeptide~~ and recovering the hexose oxidase ~~polypeptide~~ from the cultivation medium or from the transformed microbial host cell ~~organism~~.

52. (Currently amended) A method according to claim 51, wherein the hexose oxidase ~~polypeptide~~ is produced by a microbial host cell selected from the group consisting of a bacterial cell, a fungal cell and a yeast cell.

53. (Currently amended) A method according to claim 52, wherein the hexose oxidase ~~polypeptide~~ is produced by a host cell selected from the group consisting of an *E. coli* cell, a *Saccharomyces cerevisiae* cell and a *Pichia pastoris* cell.

58. (Currently amended) A composition according to claim 45, wherein the hexose oxidase ~~polypeptide~~ oxidizes at least one sugar selected from the group consisting of D-glucose, D-galactose, maltose, cellobiose, lactose, D-mannose, D-fucose and D-xylose.

65. (Currently amended) A composition ~~according to claim 45,~~ comprising a fusion polypeptide comprising a hexose oxidase encoded by a DNA fragment according to claim 9 ~~additional enzymatically active amino acid sequences~~.

66. (Currently amended) A method of manufacturing a food product with a reduced sugar content ~~wherein an isolated DNA fragment according to claim 9 is used~~ comprising,

(i) adding a microbial host cell capable of producing a hexose oxidase according to claim 11 to the food product prior to, during, or subsequent to a process step, and,

(ii) processing, storing, or packaging the food product comprising the microbial host cell capable of producing a hexose oxidase,

whereby the sugar content of the food product is reduced.

67. (Previously Presented) A method according to claim 66, wherein the food product is selected from the group consisting of a dairy product, a starch-containing product and a non-dairy product.

68. (Currently amended) A method ~~according to claim 66 wherein the polypeptide encoded by the isolated DNA fragment is acting~~ of manufacturing a food product comprising an antioxidant comprising,

(i) adding a microbial host cell capable of producing a hexose oxidase according to claim 11 to the food product prior to, during, or subsequent to a process step, and,

(ii) processing, storing, or packaging the food product comprising the microbial host cell capable of producing a hexose oxidase,

whereby the hexose oxidase produced by the host cell acts ~~as an antimicrobial agent or~~ as an antioxidant.

84. (Currently amended) A ~~polypeptide having~~ hexose oxidase according to claim 13 wherein the hexose oxidase ~~activity comprising~~ has the amino acid sequence set forth in ~~of~~ SEQ ID NO:31.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Scott Yarnell on May 13, 2004.

The following is an examiner's statement of reasons for allowance:

The examiner's amendment is the product of several telephonic discussions with Applicant's counsel between April 5 and May 13, 2004. The amendment cancels claim 8 that would have described a composition of Sullivan et al., of record, comprising an

isolated, native, *Chondrus crispus* hexose oxidase. Instead, the amendment rewrites claim 9 above to describe Applicant's essential contribution to the art, a disclosure that gives the public access, upon expiration of the patent grant, to any allele present in the genome of any member of the species *Chondrus crispus* encoding a hexose oxidase recognizable by the presence of amino acid sequences of the peptide regions listed in the claim, thus permitting the recombinant production of this versatile hexose oxidase in a host cell for isolation and use in industry and food preparation. Claims 35 and 69 that had described methods essentially redundant with methods of the preceding claims 34 and 68 are also canceled, as are claims 46, 54, and 62.

The examiner's amendment also clarifies the intended subject matters of several claims by, (1) stating in claim 9 the proper abbreviation for undesignated amino acids, "Xaa", used in the Sequence Listing filed with the instant application, (2) revising claim 13 to describe an isolated hexose oxidase recombinantly produced in a host cell that does not glycosylate the product, (3) revising claims 11, 12, 52, and 53 to more clearly describe the intended subject matters, (4) revising claim 22 to provide an alternative description of an isolated, non-glyclosylated, hexose oxidase encoded by a DNA fragment of claim 9, (5) revising claims 32, 34, 66, and 68 to describe methods of manufacture according to disclosures at pages 6, 16 and 25 of the specification, to make claims 34 and 68 independent claims, and to permit claims 66 and 68 to describe methods that rely on microbial host cells comprising a DNA fragment encoding a hexose oxidase according to claim 9, (6) restating claim 25 to describe a nucleic acid sequence that encodes a fusion polypeptide comprising a hexose oxidase encoded by a DNA fragment according to claim 9, (7) restating claim 65 to describe a composition comprising a fusion polypeptide wherein the fusion polypeptide comprises a hexose

oxidase encoded by a DNA fragment according to claim 9, and (8) generally providing a uniform format in recitations throughout the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
May 13, 2004

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